FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS: None

CLASS II RECALLS:

6515NS

MDC 12296	Lasers
PRODUCT	Model Epilaser System, used in dermatology. Recall #Z-255-8.
CODE	None.
MANUFACTURER	Palomar Medical Products, Inc., Lexington, Massachusetts.
RECALLED BY	Manufacturer.FDA approved the firm's corrective action plan on December 22, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	89 units were distributed.
REASON	The safety shutter hung open, potentially exposing users and patients to unnecessary laser radiation.

[ ] None Present
[ ] Action Taken _____
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6525NS

MDC 13469	Scanners, Computed Tomography
PRODUCT	Tomoscan AV-#1 CT Scanner, used in CT Radiography.Recall #Z-238-8.
CODE	None.
MANUFACTURER	Phillips Medical Systems, Shelton, Connecticut.
RECALLED BY	Manufacturer.FDA approved the firm's corrective action plan on January 9, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	21 units were distributed.
REASON	The units are defective under 21 CFR 1003.2 in that they do not interrupt the exposure when the tabletop movement stops during a volume scan mode.

[ ] None Present
[ ] Action Taken _____
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6525NS

MDC 13269	Radiographic Units, Dental
PRODUCT	Model No. A3 Beam Limiting Device (BLD) for the Versaview Model A3 Dental System, used in dental radiography.Recall #Z-246-8.
CODE	None.
MANUFACTURER	J. Morita Corporation, Tustin, California.

RECALLED BY	Manufacturer.FDA approved the firm's corrective action plan January 9, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	22 units were distributed.
REASON	The units are defective under 21 CFR 1010.3 and 1020.30(e) in that they do not have proper certification and identification labels on the beam limiting device.

[ ] None Present
[ ] Action Taken _____
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CLASS III RECALLS:None

MEDICAL EQUIPMENT SAFETY ALERTS:None

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.
Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than 20 MAR 98 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN).
(FOM-P), Bonnie Phillips, DSN (343-7445)

CLASS I RECALLS:

NSN	6505 Nonstandard
PRODUCT	Glycyrrhizic Acid (extract) Injection, 8 mg, 30mL vials, Rx. Recall #D-062-8.
CODE	All product purchased from April 1, 1996 thru October 10, 1996.
MANUFACTURER	Apothe'Cure, Inc., Dallas, Texas.
RECALLED BY	Manufacturer, by letter on November 25, 1996. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Canada.
QUANTITY	257 vials were distributed.
REASON	Microbial contamination - Mold in

product-aspergillus versicolor.

[ ] None Present
[ ] Action Taken _____

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CLASS I I RECALLS:

NSN	6505 Nonstandard
PRODUCT	Thyrolar 2 Tablets (Levothyroxine 100 mcg/Liothyronine 25 mcg), in 100 tablet bottles, Rx, used as a synthetic thyroid replacement therapy. NDC #0456-0055-01. Recall #D-058-8.
CODE	Lot #1975 EXP 12/98.
MANUFACTURER	Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
RECALLED BY	Forest Pharmaceuticals, Inc., St. Louis, Missouri, by letter on November 24, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	6,044 bottles were distributed.
REASON	Mislabeling - One bottle labeled as containing Thyrolar 2 was found to contain Thyrolar 1 Tablets.

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	Polymyxin B Sulfate, USP, (for Prescription Compounding), 100 million units per bottle, in bottles of 10.78 grams. Recall #D-059-8.
CODE	Lot #7D6013.
MANUFACTURER	Repacked for Coulter Foods.
RECALLED BY	Paddock Laboratories, Inc., Minneapolis, Minnesota, by telephone on December 11 and 12, 1997, followed by letter sent on December 12, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Alabama, California, Florida, Maryland, Michigan, Minnesota, New York, Texas.
QUANTITY	25 bottles were distributed.
REASON	Mislabeling - Product potency labeled as 9282 polymyxin B units/mg, but actually contains 7891 units/mg.

[ ] None Present
[ ] Action Taken _____

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NSN	6515 Nonstandard
PRODUCT	CA-300 Face Mask, Adult Medium, single use, an

accessory to the Aerotech I Aerosol Unit for the Administration Technetium Tc 99m (radioactive agent) for lung imaging. Recall #Z-251-8.

CODE Lot #0287300.

MANUFACTURER Engineered Medical Systems (EMS), Indianapolis, Indiana.

RECALLED BY CIS-US, Inc., Bedford, Massachusetts, by letter dated October 14, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Sweden.

QUANTITY 1,054 masks were distributed.

REASON Some of the masks may have a seal defect where the plastic mold joins the apex at the plastic nosepiece, resulting in a small hole.

[ ] None Present
[ ] Action Taken _____

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NSN 6515 Nonstandard

PRODUCT Ultrasound Transmission Gel, in 8 fluid ounce containers, used to provide an efficient sound coupling medium for ultrasound transmission. Recall #Z-254-8.

CODE Part #82-299, Lot #532428 EXP 8/98

MANUFACTURER Aplicare, Inc. (Previously known as Redi Products, Inc., Pritchard, West Virginia.

RECALLED BY Manufacturer, by verbally contacting all customers on November 21, 1997, followed by letter dated November 24, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 64 cases were distributed.

REASON There was mold growing between the nozzle and the nozzle cap of the applicator.

[ ] None Present
[ ] Action Taken _____

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NSN 6515 Nonstandard

PRODUCT Radiation Protective Devices:
a) Thyroid Shield;
b) Thyroid Flare;
c) Maternity Shield;
d) Aprons (One piece, two piece, half and mini);
e) Vest; f) Kilt; g) Apron Sleeve;
h) Lead Drape;
i) Fluoroscopic Spot Film Shield;
j) Table Mounted Radiation Shield (Lead vinyl Shields only);

k) Port Shield/Port Shield X-tra and replacement shields. Recall #Z-259/269-8.

CODE None.

MANUFACTURER AADCO Medical, Inc., Randolph, Vermont.

RECALLED BY Manufacturer, by letter December 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Brazil, Hong Kong

QUANTITY 700 units were distributed.

REASON The radiation protection devices contain lead contaminated with small amounts of radioactive substances.

[ ] None Present
[ ] Action Taken _____

NSN 6525 Nonstandard

PRODUCT General Radiographic Film:
a) Kodak INSIGHT Thoracic Imaging Film, 35 x 43 cm, Cat. #828 8201, emulsion #s 431 and 432
b) Kodak INSIGHT VHS Thoracic Imaging Film, 35 x 35 cm, Cat. #832 3669, emulsion # 066; 35 x 43 cm, Cat. #173 1165, emulsion #066. Recall #Z-276/277-8.

CODE emulsion #066, exp. 6/99
emulsion #431, exp. 6/99
emulsion #432, exp. 8/99.

MANUFACTURER Eastman Kodak Company, Windsor, Colorado.

RECALLED BY Eastman Kodak Company, Health Sciences Division, Rochester, New York, by letters dated November 26, 1997, and December 2, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 5,923 packs were distributed.

REASON The product was finished incorrectly, resulting in a orientation error during exposure.

[ ] None Present
[ ] Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard

PRODUCT Royal Med brand (a) Enteric Coated Aspirin Tablets, 325 mg, in 100 tablet bottles; b) Acetaminophen Tablets, 325 mg, in 100 tablet relief of minor aches, pains, and headaches, and to reduce fever. Recall #D-060/061-8.

CODE Lot #101G45 EXP 5/99.

MANUFACTURER Geri-Care Pharmaceutical Corporation, Brooklyn, New York.
RECALLED BY Manufacturer, by letter dated December 16, 1997, followed by telephone. Firm-initiated recall ongoing.
DISTRIBUTION Minnesota, California, Florida Georgia, Illinois, Massachusetts, Ohio, Pennsylvania, Texas, Washington state.
QUANTITY a) 384 bottles; b) 2,821 bottles were distributed.
REASON Mislabeling - Some bottles labeled as enteric coated aspirin contain acetaminophen.

[ ] None Present
[ ] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Recovered Plasma. Recall #B-420-8.
CODE Unit #49S71897.
MANUFACTURER American Red Cross, Tulsa, Oklahoma.
RECALLED BY Manufacturer, by letter dated September 22, 1997. Firm-initiated recall ongoing.
DISTRIBUTION California.
QUANTITY 1 unit was distributed.
REASON Blood product was collected from a donor having been diagnosed with Sarcoidosis.

[ ] None Present
[ ] Action Taken _____

NSN 6540 Nonstandard
PRODUCT OPTIMA FW (Polymacon) Visibility Tinted Contact Lenses, 6-Packs & Value Packs, -3.5 8.7mm BC. Recall #Z-256-8.
CODE Lot 7120C1AA EXP 04/2000.
MANUFACTURER Bausch & Lomb, Inc., Rochester, New York.
RECALLED BY Manufacturer, by letter dated October 20, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 11,604 lensses were distributed.
REASON Some of the blister packs may contain lenses with the incorrect refractive power of -1.25D.

[ ] None Present
[ ] Action Taken _____

NSN 6550 Nonstandard
PRODUCT dsDNA IgG/M Enzyme-Linked Immunosorbent Assay

(ELISA), for the detection of antibodies in human serum to dsDNA antigen and as an aid in diagnosis of systemic lupus erythematosus. For in vitro diagnostic use, 96 determinations per kit, labeled as follows: Wampole Laboratories, Product #427670 (domestic) and Clark Laboratories, Product #2327670 (International). Recall #Z-250-8.

CODE Lot No. 041.

MANUFACTURER Trinity Biotech (formerly Clark Laboratories, Inc.), Jamestown, New York.

RECALLED BY Manufacturer, by telephone and by letter dated December 2, 1997. Firm-initiated recall ongoing.

DISTRIBUTION New Jersey, South Africa, Australia.

QUANTITY 276 kits were distributed.

REASON The absorbance of the positive control falls below its stated range on the vial label.

[ ] None Present
[ ] Action Taken _____

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NSN 6550 Nonstandard

PRODUCT Bartels Epstein-Barr Virus IgG Enzyme Immunoassay, intended for the qualitative detection of IgG antibody to the viral capsid antigen (VCA) of Epstein-Barr Virus in human serum by the enzyme-linked immunosorbent assay (ELISA) method. Recall #Z-270-8.

CODE Lot #2101.

MANUFACTURER Gull Laboratories, Salt Lake City, Utah.

RECALLED BY Bartels, Inc., the Diagnostics Division of Intracel Corporation, Issaquah, Washington, by letter on December 16, 1997. Firm-initiated recall ongoing.

DISTRIBUTION California, Delaware, Iowa, Ohio, Pennsylvania, Puerto Rico, Texas, Washington state.

QUANTITY 91 kits were distributed.

REASON The conjugate is losing stability resulting in absorbance values for the reference and positive control that are lower than the limits specified in the product insert.

[ ] None Present
[ ] Action Taken _____

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NSN 6550 Nonstandard

PRODUCT CDC Anaerobe 5% Sheep Blood Agar with Phenylethyl Alcohol, for in-vitro diagnostic

	use. Recall #Z-281-8.
CODE	Catalog #4321739, Lot #I1RAIA.
MANUFACTURER	Becton Dickinson Microbiology Systems, Cockeysville, Maryland.
RECALLED BY	Becton Dickinson Microbiology Systems, Sparks, Maryland, by telephone and letter faxed on September 23, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Canada.
QUANTITY	8,000 units were distributed; firm estimated that 2,276 units remained on market at time of recall initiation, however, the product is now expired.
REASON	Product is contaminated with Enterococcus faecium.

[ ] None Present
[ ] Action Taken _____

NSN	6550 Nonstandard
PRODUCT	Trypticase Soy Agar with 5% sheep Blood (TSA II), for in-vitro diagnostic use. Recall #Z-282-8.
CODE	Catalog No. 4321261, Lot No. I4RAIS.
MANUFACTURER	Becton Dickinson Microbiology Systems, Cockeysville, Maryland.
RECALLED BY	Manufacturer, by letter faxed on September 23, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	11,590 units were distributed. Firm estimated that 48,768 units remained on market at time of recall initiation, however, the product is now expired.
REASON	Product is contaminated.

[ ] None Present
[ ] Action Taken _____